

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 2002N-0500]

General and Plastic Surgery Devices; Classification of Silicone Sheeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying silicone sheeting intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars into class I (general controls). As a class I device, the device will be exempt from premarket notification requirements. This action is taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Devices User Fee Modernization Act of 2002 (MDUFMA).

DATES: This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Sam R. Arepelli, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 20, 2003 (68 FR 13639), FDA issued a proposed rule to classify silicone sheeting intended to manage hyperproliferative scars on intact skin into class I based on available information regarding this device, including the recommendation of the General and Plastic Surgery Devices Panel (the Panel). The device is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars. FDA invited interested persons to comment on the proposed rule by June 18, 2003.

II. Summary of the Comments and FDA's Response

FDA received two comments on the proposed rule. One comment supported the proposed classification. The other comment expressed concerns about the proposal to classify the device into class I and exempt it from premarket notification. The comment recommended that FDA require premarket notification for silicone sheeting as recommended by the Panel. Specifically:

1. The comment stated that the proposed classification conflicts with the July 8, 2002, Panel recommendation of classification into class I subject to general controls, including premarket notification.

We agree that the Panel's recommendation was that this device be classified into class I subject to general controls, including premarket notification. Under the act, however, class I devices are presumptively exempt from premarket notification unless the class I device is "intended for a use which is of substantial importance in preventing impairment of human health," or "presents a potential unreasonable risk of illness or injury" (section 510(l) of the act (21 U.S.C. 360(l))). In response to the specific question of

whether this device is “for a use which is of substantial importance in preventing impairment of human health,” the Panel responded no. In response to the question of whether the device “present[s] a potential unreasonable risk of illness or injury,” the Panel again responded no. Thus, although the Panel’s recommendation was that FDA require premarket notification, when asked whether the device presented the specific characteristics that would prevent exempting the device from premarket notification under section 510(l) of the act, the Panel’s response was no.

As discussed in the proposed rule (68 FR 13639), FDA’s experience with similar device types, specifically four other types of wound dressings, has demonstrated that classification as class I and exemption from premarket notification provide a reasonable assurance of safety and effectiveness. FDA believes that its experience with these devices is directly relevant to this determination and supports the exemption of this device from premarket notification. As discussed later in this document, FDA also believes this device presents a low risk to health and that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device.

Finally, FDA is not required to follow the Panel’s recommendations, (section 513(b)(7) of the act (21 U.S.C. 360c(b)(7))) and for the reasons outlined in this preamble, FDA has determined that exempting this device from premarket notification requirements is appropriate.

2. The comment also stated that there is insufficient valid scientific evidence from prospective randomized clinical trials that: (1) Shows that the device is effective in either alleviating the symptoms or improving the appearance of hypertrophic or keloid scars, and (2) explains the device’s mechanism of action. The comment further stated that keloid scars are more

common among African-Americans and Asian-Americans and that no studies have investigated the effectiveness of silicone sheeting on a representative number of individuals across racial, sexual, or age categories.

FDA agrees in part. FDA reviewed the cited literature relating to this comment, as well as all other publicly available information on the device type. FDA acknowledges that the literature on this preamendments device does not demonstrate that silicone sheeting alone alleviates the symptoms or improves the appearance of hypertrophic or keloid scars, and that the literature does not focus on the performance of the device in specific ethnic or racial groups.

Consistent with the Panel's recommendation, however, FDA believes that class I is the appropriate classification for silicone sheeting intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars. This device is used in conjunction with other standard scar care treatments and provides a physical barrier between the scar and the environment, keeping the scar moist and clean, thus contributing to an improved overall outcome for the patient. The comment on the lack of consensus on the precise mechanism for action does not bear upon the safety or effectiveness of the device. The panel did discuss whether this device is appropriate for use on open wounds, however. To address these concerns, FDA has amended the intended use statement to more clearly reflect that the device is to be used in the management of closed scars.

FDA also notes that silicone sheeting for this particular intended use has a long history of safe use and that the risks to health posed by the use of the device are low. In fact, the Panel did not identify any risks to health associated with its use. Moreover, there have been only two medical device adverse event

reports for this device over a span of several decades of use. The agency believes that classifying the device as class I and exempting it from premarket notification is appropriate for a device that poses a low risk to health and that is used in conjunction with other standard treatments.

3. The comment stated that FDA should consider the risks of off-label uses of silicone sheeting and stated that the device is marketed to surgeons as intended for use in the repair of fractured orbital floors, among other uses. The comment continued

“[i]f manufacturers are permitted to market silicone sheeting for any use, without any proof of safety, then the public’s health is at risk. The labeling requirements in a premarket notification provide some measure of assurance. If silicone sheeting is classified as class I, there will be fewer safeguards to protect patients.”

FDA disagrees with this part of the comment for the following reasons:

- This comment appears to misunderstand the scope of this classification and exemption. FDA has classified into class I and exempted only silicone sheeting intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars. Silicone sheeting for other intended uses would be subject to a limitations of exemptions analysis under section 510(l) of the act and § 878.9 (21 CFR 878.9). Under this regulation, a premarket notification must be submitted when a device is intended for a use different from the intended use of a legally marketed device in that “generic type” of device (§ 878.9(a)). Thus, silicone sheeting for other intended uses may be required to submit a premarket notification. Certain uses could require a premarket approval application (PMA). This action does not authorize manufacturers to market silicone sheeting for any use other than the intended use stated in the device identification.

- The comment also states that the labeling requirements in a premarket notification provide some measure of assurance. FDA agrees that proposed labeling is required as part of the premarket notification submission (21 CFR 807.87(e)); however, the proposed labeling is submitted only as a means of describing the device and its intended use for the purpose of making a substantial equivalence determination (section 513(i)(1)(E) of the act (21 U.S.C. 360c(i)(1)(E))).

Section 513(i)(1)(E) of the act also states that, as part of a substantial equivalence determination, FDA may require information in the labeling regarding an off-label use if there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device and that such use could cause harm. In the case of silicone sheeting intended for use in the management of closed hyperproliferative scars, however, FDA does not believe that the criteria in section 513(i)(1)(E) of the act would be met. The widespread availability of medical grade silicone materials make it unlikely that silicone sheeting intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars will contribute to any significant off-label use.

The adulteration and misbranding provisions of the act (sections 501 and 502 of the act (21 U.S.C. 351 and 352)) will help ensure that the device is appropriately labeled and has a reasonable assurance of safety and effectiveness. These provisions are applicable to all devices, including class I devices exempt from premarket notification. If these provisions are violated, FDA has the authority to take enforcement action.

4. The comment stated that the proposed intended use of the device in the proposed identification statement regarding use “on hyperproliferative

(hypertrophic) scars on intact skin” is inconsistent because hypertrophic scars are considered as compromised (not intact) skin.

FDA partially agrees. On further review of the panel transcript, FDA believes that the intent of the panel was for use of the device “on closed hyperproliferative (hypertrophic and keloid) scars.” FDA is accordingly revising the identification to “Silicone sheeting is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars.”

5. Lastly, the comment urged that “as an implanted product” this device should be classified into class III.

FDA notes that the device classified is not an implanted product, but rather one intended for topical use on closed scars. Thus, this comment is not applicable to the device being classified.

III. FDA’s Conclusion

Based on a review of the available information in the preamble to the proposed rule and placed on file in FDA’s Division of Dockets Management and for the reasons stated previously, FDA concludes that general controls will provide reasonable assurance of the safety and effectiveness of silicone sheeting intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars. Therefore, FDA is classifying the device into class I.

Also, based on the reasons discussed previously, FDA believes that premarket notification is not required to provide a reasonable assurance of the safety and effectiveness of this device. Additionally, FDA believes that silicone sheeting intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars does not meet the reserved criteria in section 510(l) of the act.

IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this classification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. FDA is classifying this device into class I, the lowest level of control allowed. In addition, the device is exempt from premarket notification requirements. The agency, therefore, certifies that this final rule will not have a significant impact on a substantial number of small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires

that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount. In addition, it will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore, a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

List of Subjects in 21 CFR Part 878

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act, and the authority delegated to the Commissioner of Food and Drugs, 21 CFR part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 1. The authority citation for 21 CFR part 878 is revised to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Section 878.4025 is added to subpart D to read as follows:

§ 878.4025 Silicone sheeting.

(a) *Identification.* Silicone sheeting is intended for use in the management of closed hyperproliferative (hypertrophic and keloid) scars.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9.

Dated: July 28, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S